Syneron
Medical LTD

OCT - 3 2011

510(K) SUMMARY

eTwo Skin Treatment System

510(k) Number K 110672

Applicant's Name: Syneron Medical Ltd.
Industrial Zone
Tavor Building
Yokneam Illit 20692
Israel
Tel: (972)73-244-2200
Fax: (972)73-244-2202

Contact Person: Yoram Levy, Qsite
31 Haavoda Street
Binyamina, Israel 30500
Tel (972)4-638-8837; Fax (972)4-638-0510
Yoram@qsitemed.com

Trade Name: *eTwo Skin Treatment System*

Preparation Date: March 07, 2011

Classification: **Name**: Electrosurgical, cutting & coagulation device & accessories
Product Code: GEI, OUH
Regulation No: 21 CFR 878.4400, 21CFR 878.4810
Class: II
Panel: General and Plastic Surgery

Device Description:

The ***eTwo skin treatment system*** is a mobile operating system combining two treatment applicators:

- **Sublative RF applicator,** which is intended for dermatological procedures requiring ablation and resurfacing of the skin and for ablation and resurfacing of the skin for wrinkle treatment. **Sublative RF**'s technology enables skin remodeling with minimal downtime. In fractional treatment, small damaged areas are created in the skin, accelerating tissue healing process after treatment.

Syneron

Medical LTD

- **Sublime applicator,** which is intended for non invasive wrinkles treatment. The applicator uses pulsed infrared light combined with RF energy for Deep Tissue Stimulation leading to skin tightening. Thermal stimulation of the deep dermis contributes to collagen enrichment and tissue remodeling.

Intended Use Statement:

The **eTwo Skin Treatment system** is intended for dermatological procedures.
The **Sublative RF applicator** is indicated for Dermatological procedures requiring ablation and resurfacing of the skin, and for the treatment of facial wrinkles.
The **Sublime applicator** is indicated for non invasive wrinkles treatment."

Predicate Devices: Substantial equivalence to the following predicate devices is claimed:

Device Name	510k No	Date of Clearance
Syneron Matrix RF Applicator	**K090025**	Jan 8, 2010
Syneron Polaris WR ST Applicator	**K053616**	Mar 14, 2006
EndyMed Imagine TC Skin Treatment System	**K083461**	Jul 24, 2009

Performance Standards:

eTwo Skin Treatment System complies with:

- **EN 60601-1** Medical Electrical Equipment-Part 1: General Requirements for Safety-1. Collateral Standard: Safety Requirements for Medical Electrical Systems.
- **IEC 60601-1-2** Medical Electrical Equipment Part 1-2: Collateral Standard: Electromagnetic Compatibility – Requirements and Tests
- **ANSI AAMI 60601-2-2** safety of high frequency surgical equipment.

A detailed description appears in **Section 14.**

Syneron

Medical LTD

Summary of Clinical performance data:

The safety and efficacy of the ***eTwo Skin Treatment System*** was evaluated in the two cleared applicators that are part of this device. Syneron believes that clinical data is not required to determine the safety and efficacy of the ***eTwo Skin Treatment System.***

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Syneron, LTD
% QSite
Yoram Levy
31 Haavoda Street
Binyamina, Israel 30500

OCT - 3 2011

Re: K110672
Trade/Device Name: eTwo Skin Treatment System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI, OUH
Dated: September 4, 2011
Received: September 7, 2011

Dear Yoram Levy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Syneron
Medical LTD

INDICATIONS FOR USE STATEMENT

510(k) Number (if known):

Device Name: *eTwo Skin Treatment System*

Indications for Use: The **eTwo Skin Treatment system** is intended for dermatological procedures.
The **Sublative RF applicator** is indicated for Dermatological procedures requiring ablation and resurfacing of the skin, and for the treatment of facial wrinkles.
The **Sublime applicator** is indicated for non invasive wrinkles treatment."

Prescription Use _X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-off)
Division of General, Restorative and Neurological Devices
510(k) Number

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K110672